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No. 89-1189

In the Supreme Court of the United States

October Term, 1989

MR. AND MRS. FLOYD BROCK, individually and as next friend of RACHEL BROCK, a minor,

Petitioners,

v.

MERRELL DOW PHARMACEUTICALS INC.,

Respondent.

ON PETITION FOR WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

BRIEF IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

Should certiorari be granted where the decision below is in accord with that of the other federal circuits, holding that plaintiffs' evidence does not create a jury issue as to whether Bendectin causes human birth defects?

CORPORATE AFFILIATIONS OF RESPONDENT

Respondent Merrell Dow Pharmaceuticals Inc. is a wholly owned subsidiary of Marion Merrell Dow Inc., which is approximately 2/3 owned by The Dow Chemical Company. Their subsidiaries and affiliates that have securities in the hands of the public are the following:

Alamo Land Company, Inc.; Arabian Chemical Company Limited; Compagnie des Services Dowell Schlumberger; Chief Shipping Company; Cromarty Petroleum Company Limited; Chimtrade; Transformadora de Etileno S.A.; Vorakim Kima Sanayi Ve Ticaret A.S.; Dowell Schlumberger Canada, Inc.; Fort Saskatchewan Ethylene Storage Limited Partnership; H-D Tech, Inc.; Wabiskaw Explorations Ltd.; Haeger and Kaessner Limited; Viopal S.A.; Scotdril Offshore Company; Dow Corning Corporation; Dowell Schlumberger Corporation; Dowell Schlumberger Incorporated; El Dorado Terminals Company; Joliet Marine Terminal Trust Estate; M.D. Kasei Limited; Funai Pharmaceuticals Company Ltd.; First Chemical Factoring S.p.a.; Laboratories Industriales Farmaceuticos Ecuatorianos (L.I.F.E.); MDP (Holdings) Ltd.; Fort Saskatchewan Ethylene Storage Corporation; Oronzio de Nora Technologies BV; Oronzio de Nora Technologies S.p.a.; Pacific Chemicals Berhad; Petroquimica-Dow S.A.; P.T. Pacific Chemicals Indonesia; Vorakim Kimya Sanayi VE Ticaret A.S.; Oronzio de Nora Technologies S.p.a.; Ulsan Pacific Chemical Company Ltd.; Dow Kakoh Kabushiki Kaisha; Family Com. e Ind. de Productos de Limpeza Ltda.; Oronzio de

Nora S.A., (Lugano); Pacific Chemicals (Pakistan) Ltd.; Pacific Eurosemences, S.A.; DCU/LB Trust; Chief Shipping Company; Metal Mark, Inc.; Zip Pak Incorporated; Gurit-Essex, A.G.; Pacific Cable Products Sendirian Berhad; The Cynara Company; Dow Elanco B.V.; Etoxilados del Plata S.A.

TABLE OF CONTENTS

Page

Question Presented i

Corporated Affiliations Of Respondent iii

Table of Contents v

Table of Authorities Cited vi

Statement of The Case 1

1. The Trial 1

2. The Fifth Circuit's Reversal 3

a. The Epidemiological Studies 3

b. The "*In Vitro*" Studies 4

c. The Animal Studies 4

3. The Petition For Rehearing and for Rehearing En Banc 5

Reasons Why The Petition Should Be Denied 7

I.

There Is No Conflict Among The Circuits 7

A. The courts of appeals are as one in Bendectin cases .. 7

B. The non-Bendectin cases are decisively different 9

II.

The Petition Presents No Seventh Amendment Or *Erie* Issue 11

Conclusion 14

TABLE OF AUTHORITIES CITED

Cases

Page

Byrd v. Blue Ridge Rural Electric Cooperative,
356 U.S. 525 (1958) 12

Erie R. Co. v. Tompkins,
304 U.S. 64 (1938) 11, 12

Ferebee v. Chevron Chemical Co.,
736 F.2d 1529 (D.C. Cir.), *cert. denied*,
469 U.S. 1062 (1984) 9

Galloway v. United States,
319 U.S. 372 (1943) 10

Herron v. Southern Pacific Co.,
283 U.S. 91 (1931) 11

In re Bendectin Litigation, 857 F.2d 290
(6th Cir. 1988) *cert. denied sub nom.*,
Hoffman v. Merrell Dow
Pharmaceuticals Inc., 109 S.Ct. 788 (1989) 6

Lynch v. Merrell-National Laboratories,
830 F.2d 1190 (1st Cir. 1987) 6, 7

Neely v. Martin K. Eby Construction Co.,
386 U.S. 317 (1967) 4, 5, 10

Richardson v. Richardson-Merrell, Inc.,
857 F.2d 823 (D.C. Cir. 198 ..... 7, 9

Wells v. Ortho Pharmaceutical Corp.,
788 F.2d 241 (11th Cir.), *cert. denied*,
479 U.S. 950 (1986) 8

Wilson v. Merrell Dow Pharmaceuticals Inc.,
893 F.2d 1149 (10th Cir. 1990) 6, 7

Other Authorities

Cooper, *Directions for Directed Verdicts: A Compass for Federal Courts*, 55 Minn.L.Rev. 903 (1971) 11

9 Wright & Miller, *Federal Practice and Procedure*: *Civil* § 2525 (1971) 12

Wright, *Federal Courts* 641 (4th ed. 1983) 11

Rules

Federal Rules of Evidence

Rule 703 ..... 7, 8

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MERRELL DOW PHARMACEUTICALS INC.,

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BRIEF IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

STATEMENT OF THE CASE

1. The Trial.

Petitioners (plaintiffs below) proceeded to trial on the theory that Bendectin, a widely prescribed morning sickness medication,[1] was the cause of plaintiff Rachel Brock's birth

[1] Benedectin was approved by the Food and Drug Administration (FDA) in 1956 as safe for the treatment of nausea and vomiting in pregnancy and has been used in over 30 million pregnaancies. Respondent voluntarily discontinued the marketing of Benedectin in 1983 as the result of costs associated with litigation. Significantly, Bendectin remains approved by the FDA. As detailed *infra*, no scientist in any peer-reviewed medical or

defect, an anomaly known as Poland's Syndrome.[2] Petitioners attempted to support their theory through the testimony of expert witnesses. Among these experts was Jay Glasser, who has a Ph.D. in experimental statistics (but not epidemiology[3]). Dr. Glasser reanalyzed the data of certain previously conducted epidemiological studies, none of which had concluded that Bendectin causes birth defects. The results of Dr. Glasser's reanalysis were not statistically significant (Transcript at 1306); nonetheless, he concluded it was more likely than not that Bendectin caused Rachel Brock's birth defect. Petitioners also presented the testimony of five other experts concerning various tests conducted on animals or animal cells with Bendectin, but these experts conceded that the results of these tests could not necessarily be extrapolated to the human population and that one must rely, at least in part, on epidemiological studies to determine whether a substance is toxic in humans. On the basis of this evidence, the jury awarded petitioners $190,000 in compensatory damages and $310,000 in punitive damages against respondent Merrell Dow Pharmaceuticals Inc. (Merrell Dow). The district court denied Merrell Dow's motions for directed verdict and for judgment notwithstanding the verdict.

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scientific journal, or in any text or reference work, has ever concluded that Bendectin causes birth defects.

[2]Poland's Syndrome was first identified in 1841, and has thus been known to have existed for over 100 years prior to the development of Bendectin.

[3]As noted by the Fifth Circuit in this case, "[e]pidemiology attempts to define a relationship between a disease and a factor suspected of causing it."

2. The Fifth Circuit's Reversal.

On appeal to the Fifth Circuit, the Court of Appeals observed that, when faced with difficult medical questions of causation, "courts must critically evaluate the reasoning process by which the experts connect data to their conclusions in order for courts to consistently and rationally resolve disputes before them." (App. 7; 874 F.2d at 310.) After such an evaluation, the Court of Appeals concluded that petitioners "did not present sufficient evidence regarding causation to allow a trier of fact to make a reasonable inference that Bendectin caused Rachel Brock's limb reduction defect." (App. 20; 874 F.2d at 315.) The analysis of petitioners' evidence consisted of the following:

a. The Epidemiological Studies

As the Fifth Circuit observed, no published epidemiological study has found a statistically significant increased risk between exposure to Bendectin and birth defects in general, or limb reduction defects in particular. (App. 14; 874 F.2d at 312.) There have been approximately 40 such studies, making Bendectin one of the most studied drugs used in pregnancy. Although these studies vary somewhat in both size and methodology, the conclusions are the same: No statistically significant increased risk of limb reduction birth defects has been shown. (Transcript at 1016.) Significantly, after reviewing these studies and others, the FDA concluded in 1980 that there was no evidence that Bendectin caused birth defects. (Transcript at 864, 867.)

Petitioners attempted to overcome this wealth of epidemiological data through Dr. Glasser's "reanalysis" mentioned above. Even with such reanalysis, however, the Fifth Circuit observed that Dr. Glasser's results were not statistically significant. (App. 14; 874 F.2d at 312.) The court stated that no statistically significant studies were

presented to it or to the two other federal courts which have considered the matter. (*Ibid.*) Finally, the court noted that Dr. Glasser had not published his reanalysis for the purposes of peer review, and that courts must "be especially skeptical of medical or other scientific evidence that has not been subjected to thorough peer review." (App. 15; 874 F.2d at 313.) The court then stated: "While we do not hold that epidemiologic proof is a necessary element in all toxic tort cases, it is certainly a very important element. This is especially true when the only other evidence is in the form of animal studies of questionable applicability to humans." (App. 16; 874 F.2d at 313.)

b. The "In Vitro" Studies

In vitro studies are experiments performed on isolated tissue cells removed from living animals. Petitioners presented at trial the results of a study by Drs. Hassel and Horrigan which their experts claimed demonstrated the propensity of Bendectin to reduce the growth of "limb bud cells" taken from mice and chickens. However, Dr. Hassel himself cautioned against extrapolating the results of his study to humans because, among other things, the human body may break down Bendectin into less complex molecules which act differently than the pure test compound. (Transcript at 674.) Likewise, two of petitioners' experts theorized that the human body may metabolize Bendectin in such a way as to form toxic "metabolites," but both admitted that no studies confirm this theory. (Transcript at 181.) After reviewing this evidence, the Court of Appeals stated: "Thus, we must view the limb bud tests as quite speculative." (App. 18; 874 F.2d at 314.)

c. The Animal Studies

Petitioners' experts presented reanalyses of previously conducted animal tests and one original test that they claimed

supported their theory that Bendectin causes birth defects. There were a number of methodological flaws in this evidence, but notwithstanding these flaws, all three of petitioners'experts on this subject admitted that one must look to the human population—i.e., epidemiology—to tell whether a substance is toxic to humans.[4] Reviewing this evidence, the Court of Appeals found that it was speculative, and that "speculation unconfirmed by epidemiologic proof cannot form the basis for causation in a court of law." (App. 20; 874 F.2d at 315.) Since not one of the many epidemiological studies has shown a statistically significant association between the ingestion of Bendectin and limb reduction birth defects, the Court of Appeals reversed and rendered judgment in favor of Merrell Dow. The court stated, however, that future Bendectin cases would not be barred if new studies emerged that supported the opinions of plaintiffs' experts. (App. 20; 874 F.2d at 315.)

3. The Petition For Rehearing and for Rehearing En Banc.

In response to a petition for rehearing, the panel rendering the original opinion modified its decision by emphasizing that petitioners lacked "statistically significant" epidemiological studies rather than "conclusive" studies. (App. 21-22; 884 F.2d 166.) In response to petitioners' suggestion for rehearing en banc, the Court of Appeals voted 8-6 to deny the suggestion. Circuit Judge Reavley, writing for the six dissenters, attempted to distinguish the panel's opinion from *Richardson v. Richardson-Merrell, Inc.*, 857 F.2d 823 (D.C. Cir. 1988), *cert. denied*, 110

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[4]The Court of Appeals in its opinion stated that Drs. Thiersch and Glauser conceded this point, which they did; respondent further notes that petitioners' other animal expert, Dr. McBride, made a similar concession. (Transcript at 432.)

S.Ct. 218 (1989). According to Judge Reavley, the *Richardson* court's conclusion that plaintiffs did not present a jury question as to whether Bendectin causes birth defects was based upon a finding that plaintiff's expert lacked an adequate basis, reasonably relied upon by experts in the field, for his opinion. Judge Reavley then stated: "That record was a far cry from the one we are called upon to review here." (App. 25; 884 F.2d at 168.) However, as respondent had pointed out in its reply brief to the Court of Appeals, the evidence presented in *Brock* was virtually the same as that presented in *Richardson*.

REASONS WHY THE PETITION SHOULD BE DENIED

I.

THERE IS NO CONFLICT AMONG THE CIRCUITS.

A. The courts of appeals are as one in Bendectin cases.

This is one of many actions filed against respondent alleging that Bendectin was the cause of a plaintiff's birth defect. The various federal courts of appeals have uniformly awarded judgment in favor of Merrell Dow. This uniformity stems from an established fact: No published study has concluded that Bendectin causes birth defects in humans.

Cases involving Bendectin have been reviewed by the various courts of appeals in differing procedural postures. Some cases have proceeded to trial, resulting in jury verdicts in favor of Merrell Dow, which the appellate courts have affirmed. *In re Bendectin Litigation*, 857 F.2d 290 (6th Cir. 1988), *cert. denied sub nom.. Hoffman v. Merrell Dow Pharmaceuticals Inc.*, 109 S.Ct. 788 (1989) (affirming verdict in multidistrict litigation); *Wilson v. Merrell Dow Pharmaceuticals Inc.*, 893 F.2d 1149 (10th Cir. 1990). In other cases the courts have ruled for defendant as a matter of law. In *Lynch v. Merrell-National Laboratories*, 830 F.2d 1190 (1st Cir. 1987), the First Circuit affirmed summary judgment in favor of Merrell, agreeing with the district court that plaintiffs' evidence was too speculative to support a verdict in their favor and that their experts' opinion lacked proper foundation. 830 F.2d at 1194-1197. The court specifically found that animal studies and tests involving chemicals similar to those in Bendectin "do not have the capability of proving causation in human beings in the

absence of confirmatory epidemiological data." 830 F.2d at 1194.

This Court has recently refused to review a decision of the District of Columbia Circuit affirming the grant to defendant of judgment notwithstanding the verdict. *Richardson v. Richardson-Merrell, Inc.*, 857 F.2d 823 (D.C. Cir. 1988), *cert. denied*, 110 S.Ct. 218 (1989). The *Richardson* court, using an analysis similar to that of the First Circuit in *Lynch*, held that the jury could not properly reject the "overwhelming body" of epidemiological evidence indicating that Bendectin does not cause birth defects. 857 F.2d at 830. The court noted the extensive studies, none of which concluded that Bendectin is teratogenic, and concluded:

> Uniquely to this case, the law now has the benefit of twenty years of scientific study, and the published results must be given their just due.

857 F.2d at 832.[5]

In the present case, the Fifth Circuit followed the lead of the *Lynch* and *Richardson* courts: it gave the published epidemiological studies their just due. Epidemiological studies are crucial because their focus is on the human population, rather than animals, and a reasonable jury cannot conclude that Bendectin is a teratogen when the epidemiological data is uniformly to the contrary.

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[5]In affirming a jury verdict for defendant, the Tenth Circuit also has thought it "particularly significant" that there was uncontradicted evidence "that of the approximately forty epidemiological studies of Bendectin, none has shown a statistically significant association between ingestion of the drug and incidence of birth defects generally or limb defects in particular." *Wilson v. Merrell Dow Pharmaceuticals Inc.*, 893 F.2d 1149, _____ (10th Cir. 1990).

Petitioners seek to make much of the fact that in *Lynch* and *Richardson* it was held that plaintiffs had failed to sustain their burden of proof because the opinions of their experts were inadmissible under Rule 703 of the Federal Rules of Evidence, while here the Fifth Circuit panel reached the same conclusion based more upon a traditional "sufficiency of the evidence" analysis.[6] This is a distinction without a difference. The sufficiency of the evidence to create an issue for the jury and the adequacy of the foundation for an expert's opinion under Rule 703 are both questions of law for the court. Whether the court finds the foundation so lacking that it holds that the expert's opinion should not have been received or whether the court holds that the evidence, even if admissible, does not support the inference necessary to a plaintiff's case does not alter the result: the overwhelming scientific findings are such that no reasonable jury could find that Bendectin causes birth defects.

B. The non-Bendectin cases are decisively different.

The decision below is limited by its terms to Bendectin cases. The panel expects the decision to have "a precedential effect on other cases pending in this circuit which allege Bendectin as the cause of birth defects", though noting that it

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[6]The opinion below includes a Rule 703 type of analysis. For example, the opinion states that "courts must critically evaluate the reasoning process by which the experts connect data to their conclusions in order for courts to consistently and rationally resolve the disputes before them." (App. 7; 874 F.2d at 310.) Similarly, after observing that the D.C. Circuit in *Richardson* "affirmed its willingness to look behind the conclusions of experts," the court stated: "We too, have chosen to take the same approach as the *Richardson* court . . . ." (App. 10-11; 874 F.2d at 311.) Although it is reasonable to read *Brock* as employing a Rule 703 type analysis, such a reading is not essential here.

would not stand as a bar even in future Bendectin cases if new scientific studies suggest otherwise. (App. 20; 874 F.2d at 315.) Petitioners attempt to give the appearance of a conflict by pointing to other cases involving products other than Bendectin in which the scientific evidence was very different from what it is with regard to Bendectin. The most prominent of these is *Wells v. Ortho Pharmaceutical Corp.*, 788 F.2d 241 (11th Cir.), *cert. denied*, 479 U.S. 950 (1986), involving a spermicide called Ortho-Gynol. In that case, however, "[p]laintiffs presented several epidemiological studies that indicated an association between spermicide use and deleterious effects on the fetus."788 F.2d at 744. It is one thing, as in *Wells*, to allow the factfinder to choose when the scientific evidence is inconclusive. It would be something very different to allow the factfinder to draw an inference that is contradicted by all of the many epidemiological studies.

The thorough and conclusive nature of the studies conducted on Bendectin serves also to distinguish this case from the other non-Bendectin decisions cited by petitioners. A leading case among those is *Ferebee v. Chevron Chemical Co.*, 736 F.2d 1529 (D.C. Cir.), *cert. denied*, 469 U.S. 1062 (1984). *Ferebee*, which was heavily relied on by the Eleventh Circuit in the *Wells* case just discussed, was distinguished on this very ground by the court that had decided it, the District of Columbia Circuit, in *Richardson*.. As Judge Robinson put it:

> . . . *Ferebee* stands for the proposition that courts should be very reluctant to alter a jury's verdict when the causation issue is novel and "stand[s] at the frontier of current medical and epidemiological inquiry. . . .
>
> The case before us, however, is not like *Ferebee*. Indeed, we are at the other end of the

> spectrum, a great distance from the "frontier of current medical and epidemiologial inquiry." And far from a paucity of scientific information on the oft-asserted claim of causal relationship of Bendectin and birth defects, the drug has been extensively studied and a wealth of published epidemiological data has been amassed, none of which concluded that the drug is teratogenic.

857 F.2d at 832 (emphasis deleted).

Not one of the cases cited by petitioners involves a product that has been studied as extensively, and with such uniform results, as Bendectin. Comparing the present case to non-Bendectin cases cannot serve to create a conflict among the circuits where none exists.

II.

THE PETITION PRESENTS NO SEVENTH AMENDMENT OR *ERIE* ISSUE.

Petitioners—probably in common with all petitioners who come here to object that a lower court has taken away a jury verdict in their favor—claim that the Seventh Amendment has been violated. Doubtless they think that they are more likely to get this Court's attention with a claim of "an error of constitutional dimension" (Petition at 8) than if they describe it as what it is: a claim that, in their view, the lower court has erred in the way it applied well-settled rules about sufficiency of evidence to a highly particular factual situation.

The Seventh Amendment does not guarantee a jury determination of all issues of fact. It prohibits reexamination of a fact tried by a jury only "otherwise . . . than according to the rules of the common law." It is well settled that the district courts and the courts of appeals have both the power and the duty to direct a verdict, or to set aside a verdict if one

has been returned, if the evidence was not sufficient to make an issue for the jury. *Neely v. Martin K. Eby Construction Co.*, 386 U.S. 317 (1967); *Galloway v. United States*, 319 U.S. 372 (1943). The rules a court must apply in testing whether there was an issue for the jury to decide have been stated and restated and are well-understood. "No one disagrees with the rules but only as to their application in a particular case." Wright, *Federal Courts* 641 (4th ed. 1983).

The court below fully understood the rules. It stated them accurately, but it went on to note the difficulty in applying "general and abstract formulations" to "the concrete factual situation at hand." (App. 3-4; 874 F.2d at 308-309.) It was well aware of the need for it to distinguish between reasonable inferences, which are within the sphere of the jury, and the unreasonable inferences, which a jury cannot be allowed to draw. It recognized the wisdom of Dean Cooper's description of this task:

> It is commonplace that in large part the problem of defining the range of reasonable inference is dependent on the unique circumstances of each particular case. No self-applying rule can be offered for determining what inferences are reasonable.

Cooper, *Directions for Directed Verdicts: A Compass for Federal Courts*, 55 Minn.L.Rev. 903, 956 (1971) (quoted App. 4 n. 4; 874 F.2d at 309 n. 4).

It was that recognition that caused the court below to take as its compass cases involving Bendectin, rather than cases with very different records and different scientific evidence involving Ortho-Gynol and other products. That is also why the application of the familiar rules of sufficiency to

"the unique circumstances" of a particular case is not a task worthy of the limited time of this Court.

There is a sense, however, in which the Seventh Amendment is relevant here. It is at least in part because of the Seventh Amendment that there is nothing to petitioners' claim that the decision below is contrary to the doctrine stemming from *Erie R. Co. v. Tompkins*, 304 U.S. 64 (1938). The Seventh Amendment defines, for federal courts, when an issue is for the jury and when it must be decided as a question of law by the court. There is no reason to think that the Texas rules on sufficiency of the evidence differ from those applied in the federal courts, but if they did, it is clear that the federal court would be obliged to follow the federal test, rather than the state test. "[S]tate laws cannot alter the essential character or function of a federal court." *Herron v. Southern Pacific Co.*, 283 U.S. 91, 94 (1931). In a federal action for personal injuries, if the evidence is insufficient to make a jury issue "and the question is one of law, the judge has the right and duty to direct a verdict for the defendant." 283 U.S. at 96. "[T]here is a strong federal policy against allowing state rules to disrupt the judge-jury relationship in the federal courts." *Byrd v. Blue Ridge Rural Electric Cooperative*, 356 U.S. 525, 538 (1958). See also 9 Wright & Miller, *Federal Practice and Procedure: Civil* § 2525 (1971).

Petitioners further assert that the *Erie* doctrine is threatened because the Fifth Circuit's opinion has "expressly reallocated" their burden of proof by requiring them "to prove the association between Bendectin and limb reduction defects to a degree of likelihood of at least ninety-five percent." (Petition at 18-19.) Such statements stem from petitioners' confusion between "statistical significance" and "preponderance of the evidence." Statistical significance, insofar as it relates to this case, emanates from the world of

epidemiology. When an epidemiologist arrives at a figure of "relative risk" (i.e., whether there is an association between exposure and outcome), that figure may or may not reflect the true relative risk in the total population. Therefore, using statistical methods, an epidemiologist uses "confidence intervals" and is able to state, with some degree of certainty (usually 95%), that the relative risk will fall somewhere between the two confidence intervals.[7] The use of such confidence intervals does not result, however, in altering the standard of proof for civil trials. Instead, such tests reflect the standard selected by science as the threshold level of reliability of epidemiological data. Thus, statistical significance is related to an altogether different aspect of civil litigation, not the standard of proof for juries but the standard of reliability for scientific tests.

The Court of Appeals did not depart from the traditional "preponderance of the evidence" test in this case, and thereby create some kind of new "federal common law." Rather, it simply held that petitioners' proof did not rise to the level of a preponderance: petitioners could not have the benefit of an inference that flies in the face of twenty years of scientific research.

CONCLUSION.

The decision below is in harmony with those of the other federal appellate courts that have addressed the issue. It

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[7]Using the Heinonen study cited by the Fifth Circuit in this case as an example, the relative risk was 0.97, with confidence intervals of 0.75 and 1.26. Professor Heinonen could thus state with 95% certainty that the actual relative risk for the total human population fell somewhere between 0.75 and 1.26. As the Court of Appeals observed, a relative risk of 1.0 means no association between exposure and outcome; further, if the confidence intervals include 1.0, the study is deemed to be not statistically significant. (App. 12-13; 874 F.2d at 312.)

correctly applies settled principles about sufficiency of the evidence to create a jury issue. The petition for certiorari should be denied.

Respectfully submitted,

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County of Los Angeles

I, the undersigned, say: I am and was at all times herein mentioned, a citizen of the United States and a resident of the County of Los Angeles, over the age of eighteen (18) years and not a party to the within action or proceeding; that my business address is 11333 Iowa Avenue, Los Angeles, California 90025; that on February 20, 1990, I served the within *Brief in Opposition to Petition for Writ of Certiorari* in said action or proceeding by depositing true copies thereof, enclosed in a sealed envelope with postage thereon fully prepaid, in the United States mail at Los Angeles, California, by Express Mail, addressed as follows:

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Betty J. Malloy

(Original signed)